

**Remarks**

Claims 1, and 3-13 were pending. Claim 14 has been canceled (without prejudice to future prosecution of the claim). Claims 15-20 are hereby added. The Examiner has withdrawn the enablement rejection.<sup>1</sup> Only one rejection remains:

- I.     Claims 1 and 3-13 are rejected under 35 USC § 103(a) as allegedly being unpatentable over United States Patent No. 4,748,018, in view of Uemura et al., as evidenced by Merck Manual.

**I.     The Claims Are Not *Prima Facie* Obvious**

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference(s) themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991); and MPEP § 2142; Establishing A Prima Facie Case Of Obviousness. The Examiner is reminded that if ONLY ONE of the above requirements is not met, then a *prima facie* case of obviousness does not exist. The Applicants submit that the Examiner's rejection does not meet these criteria. The Applicants rebut the establishment of a *prima facie* case of obviousness by the argument below.

**A.     The Examiner Provides Only Conclusory Statements**

The Examiner states that the claims are rejected under 35 USC § 103(a) "for the reasons set forth in the office action mailed on 1/25/07." However, in the 1/25/07 Office Action the Examiner simply makes the conclusory statement that "it would have been obvious to one having ordinary skill in the art . . . to employ *Clostridium perfringens* being a pathogen for food poisoning or gastric diseases as taught by Uemura et al. into the therapeutic method and the composition using oral administration of avian antibodies

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<sup>1</sup> As a result, progress was made. Consequently, a "final" office action is inappropriate as set forth in the Request to Withdraw Finality, submitted herewith.

... as taught by the '018 Patent." (1/25/07 Office Action, page 4). The Examiner is asked to take note of the recent Supreme Court opinion which says that a specific showing by the Examiner is required and that conclusory statements are not sufficient:

Often, it will be necessary ... to look to interrelated teachings of multiple patents ... in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See, *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere **conclusory** statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). *KSR v. Teleflex, Slip Op No. 04-1350 (April 30, 2007)*(*emphasis added*).

In this regard, why on earth would one skilled in the art read the Merck Manual, which teaches only antibiotics for *C. perfringens*, and resort to the '018 Patent methods which require two weeks or more for generating tolerance? There is nothing in the Merck Manual to suggest oral antibody therapy (see Second Declaration of Dr. Stafford, paragraph 6). There is nothing in Uemura et al, to suggest oral antibody therapy (see Second Declaration of Dr. Stafford, paragraph 7). The Examiner is not free to ignore the fact that the Merck Manual suggests a different solution for *C. perfringens*, namely antibiotics. Moreover, the Examiner is not free to ignore the teachings in the '018 Patent that indicate tolerance is a requirement.

The Examiner argues that the claims of the present invention are "not limited to a subject who is not previously exposed to the antibody." (8/22/07 Office Action, p. 3). It must be stressed that the basis for combining the art is a separate question from the scope of the claims. Thus, one skilled in the art would ask: do I want to use antibiotics or do I want to resort to this time-consuming method of the '018 Patent? Common sense dictates that antibiotics are the easier route than what is offered by the '018 Patent and thus the practical route for food poisoning. There is no rational underpinning to support the Examiner's combination or conclusion that an antibody based approach for *C. perfringens* is obviousness. One skilled in the art would simply view the '018 Patent approach to be not practical. (See Second Declaration of Dr. Stafford, paragraph 5).

**B. The ‘018 Patent Does Not Teach *C. perfringens* and Requires Further Steps In Order to Induce Tolerance**

The Examiner acknowledged in the Office Action dated 01/25/07 that the ‘018 Patent does not teach anything about *C. perfringens*. The Examiner also appears to acknowledge that the ‘018 Patent requires tolerance. However, the Examiner makes two (2) technical errors in response to the tolerance argument.

First, the Examiner argues that the ‘018 Patent “teaches the tolerance is developed by the subsequent administration of antibody.” Dr. Stafford points out the ‘018 Patent teaches tolerance is generated in people “previously fed a material containing antibodies . . .” Thus, it appears the Examiner has made an incorrect reading of the ‘018 Patent. (See Second Declaration of Dr. Stafford, paragraph 3).

Second, the Examiner argues that the present invention “implicitly requires developing tolerance as well.” (8/22/07 Office Action, p. 3). This is simply naked speculation on the part of the Examiner that is completely rebutted by Dr. Stafford and his citation to immunology papers, as well as to statements within the ‘018 Patent. Dr. Stafford points out that tolerance requires weeks to months. (See Second Declaration of Dr. Stafford, paragraph 4). Thus, the Examiner’s interpretation of the multiple administrations in Example 6 (which amount to only a matter of hours) is completely unsupported given the rapid time course of the animal experiments. (See Second Declaration of Dr. Stafford, paragraph 4).

**C. The Examiner Has Ignored The “Consisting Essentially” Language**

The Examiner argues that “consisting essentially of” in Claim 8 “is being interpreted as ‘comprising’ for the examination purpose.” The Examiner cites to no authority for this proposition. MPEP 2111.03 indicates that “consisting essentially of” limits the claims to those steps specified and those steps that do not materially affect the basic and novel characteristics of the claimed invention. Only in the case where there is no “clear indication in the specification or claims of what the basic and novel characteristics actually are,” AND where the applicant has made no “showing that the introduction of additional steps or components would materially change the characteristics of applicant’s invention,” can the language be treated as “comprising.” In

the present case novel characteristics are clear (oral antibody therapy for *C. perfringens*). Moreover, the Second Declaration of Dr. Stafford (at paragraph 5) makes a showing that the introduction of additional steps (weeks and months of inducing tolerance) would materially and negatively impact the claimed invention set forth in Claim 8.

Without waiving the above argument in any manner, Applicants have added Claims 15-20, wherein the preamble of Claim 15 specifies “consisting.” MPEP 2111.03 makes it clear that this transitional phrase excludes any step not specified in the claim. Thus, generating tolerance is excluded.

#### **D. Further Evidence Of Non-obviousness**

The Examiner previously provided some 2004 paperwork from the Arizona Department of Health concerning *C. perfringens*. However, under the section “Prophylactic Treatment” there is absolutely no discussion of antibodies. This is further evidence that even those skilled in the health field are unaware of the preventative value of oral antibodies in this context. The Examiner does not address this point in the present office action.

#### **CONCLUSION**

Applicants believe that the arguments and evidence set forth above traverse the Examiner's rejections and, therefore, request that these grounds for rejections be withdrawn for the reasons set forth above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

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